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Patient-Specific Rehearsal Feasibility Before Endovascular Repair of Ruptured Abdominal Aortic Aneurysm

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Abstract

Purpose: To evaluate the feasibility of a patient-specific rehearsal (PsR) before emergency endovascular aneurysm repairs (eEVAR) and its influence on the operation. **Materials and Methods:** From February 2016 to October 2016, 10 consecutive patients (mean age 75±7.4 years; 9 men) presenting with a ruptured abdominal aortic aneurysm (rAAA) suitable for standard EVAR were enrolled in the study. A 3-dimensional (3D) model of the abdominal aorta was generated on a virtual reality simulator based on the patient's computed tomography (CT) images. Following the patient-specific simulation setup, PsR was conducted during patient admission or in parallel with the preoperative eEVAR workup. Measured outcomes were PsR feasibility only in the first 4 patients and impact on operative performance thereafter (changes in device selection, the planning process, clinical outcomes, perioperative mortality, and complication rates). Technical metrics and timing of system setup, rehearsal, interval from patient arrival to the actual procedure, and eEVAR were recorded. **Results:** Mean time for 3D model creation was 21.3±7.8 minutes (range 13–37); there was a significant positive relationship between aortic neck diameter and segmentation time (p=0.003). The overall mean time for simulator setup and PsR was 54±14 minutes (range 37–80); PsR alone was completed in a mean 31±40 minutes (95% confidence interval −60 to −2.2). The actual eEVAR procedure duration was 69±16 minutes (range 45–90). No delay in the actual eEVAR procedure was registered owing to the PsR pathway. In 6 patients, preprocedure rehearsal induced changes in operative strategy, including device selection, main body introduction side, and/or deployment configuration. In 4 cases, rehearsal was performed twice to achieve optimal performance. **Conclusion:** PsR before eEVAR was feasible in all cases and caused no time delays in the actual eEVAR procedure. PsR optimized eEVAR planning by identifying optimal strategy for stent-graft component selection and deployment.

Keywords

abdominal aortic aneurysm, endovascular aneurysm repair, patient-specific rehearsal, ruptured aneurysm, simulation

Introduction

Reports of the first successful emergency endovascular aneurysm repair (eEVAR) opened a new era in the management of ruptured abdominal aortic aneurysm (rAAA).[1,2] The advantages of eEVAR over open repair are less invasiveness, decreased risk from surgical bleeding, minimized hypothermia, and no deep anesthesia.[3–8] Nevertheless, conventional open repair for rAAA is still performed in many centers owing to unsuitable anatomies for the available stent-graft(s), lack of endovascular experience, and inadequate logistics.

To increase eEVAR feasibility, standardized algorithms have been developed,[9,10] which have led to excellent results with an "eEVAR whenever possible approach."[9] Other relevant eEVAR limitations relate to procedure planning, as well as device and configuration selection in an emergency setting. Patient-specific virtual reality rehearsal (PsR) enables the physician and team to practice "real" cases on a virtual patient prior to performing the procedure on the actual patient. This study examined the hypothesis that PsR in patients presenting with rAAA could optimize eEVAR operative strategy without delaying the actual eEVAR procedure, which to the best of our knowledge has not yet been reported.

Materials and Methods

Patient Selection

From February 2016 to October 2016, all patients presenting with rAAAs suitable for EVAR with standard bifurcated stent-grafts were eligible for inclusion in the pre-eEVAR PsR study. Patients requiring conventional open repair or

presenting pararenal/suprarenal AAA were excluded from participation. Written informed consent was obtained for the procedure and for the anonymous data collection, simulation, and analysis for this specific study.

Before determining EVAR feasibility, all patients with rAAA underwent preoperative workup in the emergency room and were managed as described elsewhere.[5,11] During the study period the preoperative protocol for rAAA was consistent. The anatomic severity grading (ASG) scale from the Society for Vascular Surgery was used to describe the anatomic features and complexity of the rAAA.[12] An experienced (>50 cases) local researcher recorded information on timing, clinical condition, and availability of computed tomography angiography (CTA) in order to set up the PsR simulator. An in-hospital thoracoabdominal CTA scan was performed if not provided by the referring center. A vascular surgeon and interventional radiologist team in the real-life eEVAR setting performed anatomic measurements on a PACS (picture archiving and communication system) (IMPAX; Agfa HealthCare NV, Mortsel, Belgium).

System Setup

A local researcher and an experienced vascular surgeon used compact discs (CD) containing CTA data in DICOM (Digital Imaging and Communications in Medicine) format to build a 3-dimensional (3D) model with the Procedure Rehearsal Studio (PRS) software (3D Systems USA, Cleveland, OH, USA). To reconstruct the aortoiliac data, vessel segmentation was initiated in a partially automated fashion. Manual augmentation was employed if the aortic rupture caused insufficient contrast enhancement due to hemodynamic instability, thus reducing CTA quality (high-quality CTA was defined by a fully contrasted aortoiliac segment, without mixed venous phase and no metal artifact from implants). By the same token, the celiac trunk, superior mesenteric artery, and renal arteries were reconstructed with manual augmentation. Arterial vessel calcifications were automatically reconstructed.

Centerline assignment was semiautomatically processed for the aortoiliac segment and always manually processed for the renovisceral branches. A careful alignment of renal and iliac artery centerlines is mandatory to reduce the risk of intraoperative aortic branch coverage and type I endoleak. Anatomic measurements were performed in all cases. Subsequently, 5 bone landmarks were fused with the arterial reconstruction to anchor and align the vasculature with the rest of the anatomy in the simulator. This final 3D reconstruction was exported into the Angio Mentor Dual Slim Simulation System (3D Systems USA) to conduct the rehearsal. All these steps, including DICOM file download to the software, segmentation, centerlines, landmarks, measurements, and 3D exporting into the simulator system, were recorded in field notes by the local researcher.

Rehearsal

The preoperative rehearsal was carried out by an experienced vascular surgeon and a local researcher in a dedicated office environment with no resemblance to a real operating environment and without fluoroscopy capabilities. A 3D image overlay was used to reduce the rehearsal time and increase the confidence with anatomic characteristics. The optimal C-arm angulations for the aortic neck and iliac bifurcations were registered. As in a real-life setting, device selection was performed with an oversizing of 20% to 30%. Anatomic measurements and device selection were performed by the researcher and an experienced vascular surgeon. All the materials used during the rehearsal were recorded. At rehearsal completion, a final angiogram was performed to assess outcomes, including a report on detected endoleaks by the PRS software.

The study included a PsR feasibility period (first 4 patients) and a PsR application period thereafter. In the early period, operators involved in the actual eEVAR procedure did not participate in the PsR. During the application phase, however, a vascular surgeon from the actual eEVAR team was involved in the PsR and reported the results to the surgical team before performing eEVAR.

Patient Sample

During the study period 13 consecutive patients with rAAA were admitted at our institution; 3 were excluded because 1 refused and the other two had transrenal or pararenal aneurysms requiring the parallel graft technique. The remaining 10 patients (mean age 75±7.4 years; 9 men) were enrolled

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Table 1. Demographics and Anatomic Characteristics of the 10 Patients in the Pilot Study.[a]

Age, y	75±7.4 (64–88)
Men	9
Referred	6
Conscious	9
Retroperitoneal hematoma	9
ASA 4	9
SBP, mm Hg	112.4±29.4 (65–153)
DBP, mm Hg	70.8±19.1 (40–93)
HR, bpm	91.9±12 (75–110)
Hb, g/L	108.5±17.4 (86–138)
Hct, %	32.9±4.4 (27–40)
SpO_2, %	97±1.3 (95–99)
Aortic neck diameter, mm	26.5±3.8 (19–31)
Aortic neck length, mm	17±11.1 (4–34)
Maximal sac diameter, mm	80.1±21.3 (50–123)
ASG score	19.1±5 (8–24)

Abbreviations: ASA, American Society of Anesthesiologists; ASG, anatomic severity grading scale; DBP, diastolic blood pressure; Hb, hemoglobin; Hct, hematocrit; HR, heart rate; SBP, systolic blood pressure; SpO_2, peripheral oxygen saturation.
[a]Continuous data are presented as the mean ± standard deviation (range); categorical data are given as the number.

in the study. The mean aneurysm maximum transverse diameter was 80.1±21.3 mm (range 50–123). At hospital arrival 9 patients were conscious with retroperitoneal hematoma; the other patient with free rupture in the peritoneum was unconscious and hemodynamically unstable. Six patients were referred from regional centers with CT scans, but one was without contrast enhancement and required a new CT scan. Patient demographics and preoperative findings are summarized in Table 1.

Actual eEVAR Procedure

All of the real-life eEVAR procedures were carried out in a fully equipped hybrid operating room (Philips Allura FD20 ORT; Philips Medical Systems, Inc, Shelton, CT, USA) or in a dedicated angiography suite (Artis zeego; Siemens AG, Forchheim, Germany) by a team of vascular surgeons and an interventional radiologist. All the eEVARs were performed percutaneously under local anesthesia; either an Endurant II (Medtronic Vascular, Santa Rosa, CA, USA) or an Excluder stent-graft (Gore Medical, Flagstaff, AZ, USA) was implanted. During the real-life procedures, the local researcher was in charge of monitoring and documenting steps in the procedure.

Outcomes

Outcome measurements included timing of system setup (CTA quality evaluation, segmentation, modeling of virtual 3D anatomy, etc), rehearsal, interval from patient arrival to the actual procedure, and duration of procedure. Changes in device selection and the planning process (device selection, C-arm angulation, stent-graft deployment side, and gate cannulation) were recorded. In addition, clinical outcomes, perioperative mortality, and complication rates were also tracked.

Table 2. CT Quality and 3-Dimensional Model Reconstruction Timing.[a]

CT in referral center	6
CTA slice thickness, mm (arterial phase)	1.9±1.2 (1–5)
CTA slices (arterial phase)	351.2±161.3 (160–701)
CTA high quality	4
Importing DICOM files, min	3.8±2.1 (2–8)
Segmentation, min	8.9±4.4 (3–16)
Centerline, min	5.5±3.2 (2–11)
Measurements, min	5.4±1 (3–6)
Landmarks, min	1.9±0.9 (1–3)
Exporting to simulator, min	1.2±0.4 (1–2)
Total, min	26.7±8.2 (18–43)
Total without measurements, min	21.3±7.8 (13–37)

Abbreviations: CT, computed tomography; CTA, computed tomography angiography; DICOM, Digital Imaging and Communications in Medicine.
[a]Continuous data are presented as the mean ± standard deviation (range); categorical data are given as the number.

Statistical Analysis

Data are presented as the mean ± standard deviation (range). Nonparametric tests were applied for data analysis. Baseline characteristic differences between groups (simulation vs suggested plan vs actual procedure) were assessed with one-way analysis of variance. Differences between the groups were assessed using the *t* test for continuous variables and the Pearson chi-square test for categorical variables; outcomes are provided with the 95% confidence interval (CI). A bivariate correlation test (*r*) was used to assess relationship significance. Statistical significance was assigned at a 2-sided $p<0.05$. Data analysis was performed using SPSS software (version 21.0; IBM Corporation, Armonk, NY, USA).

Results

System Setup

In 6 cases, it was necessary to burn a CD from the local PACS, which took overall 3.67±1.5 minutes (range 2–6). In 3 cases, the segmentation process did not start automatically, necessitating manual enhancement. Mean time for 3D reconstruction was 21.3±3 minutes (range 13–37). Aortic neck diameter significantly influenced segmentation time (r=0.83, n=8, p=0.003) because large aortas in association with the patient's hypotensive status reduced contrast distribution. CTA quality and 3D model reconstruction timing are summarized in Table 2.

Table 3. Device Selection for the 10 Procedures.

	Rehearsal[a]	Suggested Plan[a]	Real Life[a]	p[b]
MB side R / L	8 / 2	6 / 4	6 / 4	0.549
Ballerina	8	7 (n=9)	7 (n=9)	0.991
MB Endurant	8	8	8	>0.999
MB diameter, mm	32.7±3.2 (28–36)	33.1±3.2 (28–36)	32.7±3.7 (28–36)	0.995
MB distal diameter, mm	15.7±0.7 (15–16)	15.7±0.7 (15–16)	15.7±0.7 (15–16) (n=9)	0.992
MB length, mm	159.6±15.1 (124–170)	152.1±30.1 (70–170)	135.3±32.9 (70–170)	0.146
CL Endurant	8	7	6	0.621
CL diameter, mm	17.5±4.3 (13–28)	17.5±4.3 (13–28)	16.4±2 (15–20)	0.233
CL length, mm	145.5±24.4 (120–199)	138.7±25.4 (120–199)	125.6±10.9 (120–156)	0.048
Ext R / L	5 / 1	3 / 1	6 / 5	0.466
Ext Endurant	5	3	7	0.681
Ext diameter, mm	17.3±3.2 (13–20)	17.7±4 (13–20)	18.4±5.2 (12–28)	0.797
Ext length, mm	95.8±23 (70–120)	89.75±24 (70–120)	94.1±18.6 (70–120) (n=11)	0.900
Number of components	2.6±0.5 (2–3)	2.4±0.5 (2–3)	3.1±0.9 (2–5)	0.067

Abbreviations: CL, contralateral limb; Ext, extension; L, left; MB, main body; R, right.
[a]Continuous data are presented as the mean ± standard deviation (range); categorical data are given as the number.
[b]Analysis of variance among the 3 groups.

Device Selection and Procedure Strategy

Six patients received an Endurant II stent-graft, 3 had the Endurant II combined with Excluder limbs, and the remaining patient was treated with an Excluder stent-graft. The mean stent-graft oversizing at the proximal landing zone was 22.3% (95% CI 14.6% to 30%) larger than the native aortic diameter. Devices used in PsR and the real-life procedure are compared in Table 3.

In 4 cases, rehearsal was performed twice due to unsatisfactory initial results on PsR and subsequent changes in the suggested plan in 3 patients [main body introduction side (n=1), proximal stent-graft diameter (n=1), endograft deployment in the ballerina configuration (n=1; Figure 1), and type of device (n=1)]. Overall, after rehearsal, the initial plan changed in 5 patients, including device selection (n=3), main body introduction side (n=2; Figure 2), and endograft deployment in the ballerina configuration (n=1). Other changes in the length of the stent-graft components were mainly influenced by "in-house" stock availability. In the 4-patient feasibility period C-arm angulations did not differ significantly between the suggested plan and the real procedure; in all other cases the angulations were the same.

Clinical Outcomes

In this initial experience, PsR was feasible in all cases presenting with rAAA and treated by standard eEVAR. PsR was performed in parallel to the standard preparatory pathway, without delaying eEVAR, even in hemodynamically unstable patients. One patient with an ASG score of 8 demonstrated at rehearsal a type Ia endoleak. The same endoleak was observed during the actual procedure and required additional proximal balloon molding (Figure 3).

The time interval from patient arrival in the shock room to rehearsal completion was 130.9±72.9 minutes (range 57–260; Figure 4); the mean time from patient arrival to the actual eEVAR start was 162±95 minutes (range 38–331). Total time for simulation setup and rehearsal was 54±14 minutes (range 37–80). Mean time between rehearsal completion and eEVAR start was 31±40 minutes (95% CI −60 to −2.2, p=0.038). Only in 1 patient was the rehearsal completed 6 minutes after the actual procedure start. The real-life procedure duration was 69±16 minutes (range 45–90).

No perioperative mortality was registered in this cohort, and median in-hospital stay was 7 days (range 3–127). Perioperative complications requiring reinterventions were registered in 3 cases. The first case was reported in the initial feasibility period when the real-life surgical team was not directly involved in PsR and results of the rehearsal were not conveyed to the team. The patient was found to have a type Ia endoleak on the CTA performed on postoperative day 3; the leak, which was evident in the rehearsal, was treated endovascularly on postoperative day 7. Stent-graft kinking developed in the second patient and was treated on postoperative day 10 by relining with kissing stents; this event was not detected in the rehearsal. In 1 patient, an abdominal compartment syndrome was managed with decompression laparotomy. Renal artery coverage and/or limb occlusion did not occur either in real life or during PsR.

Discussion

Emergency EVAR for rAAA has gained increasing acceptance owing to its less invasive nature and related advantages. However, up to half of patients with rAAA have challenging proximal and distal anatomy (short and angulated landing

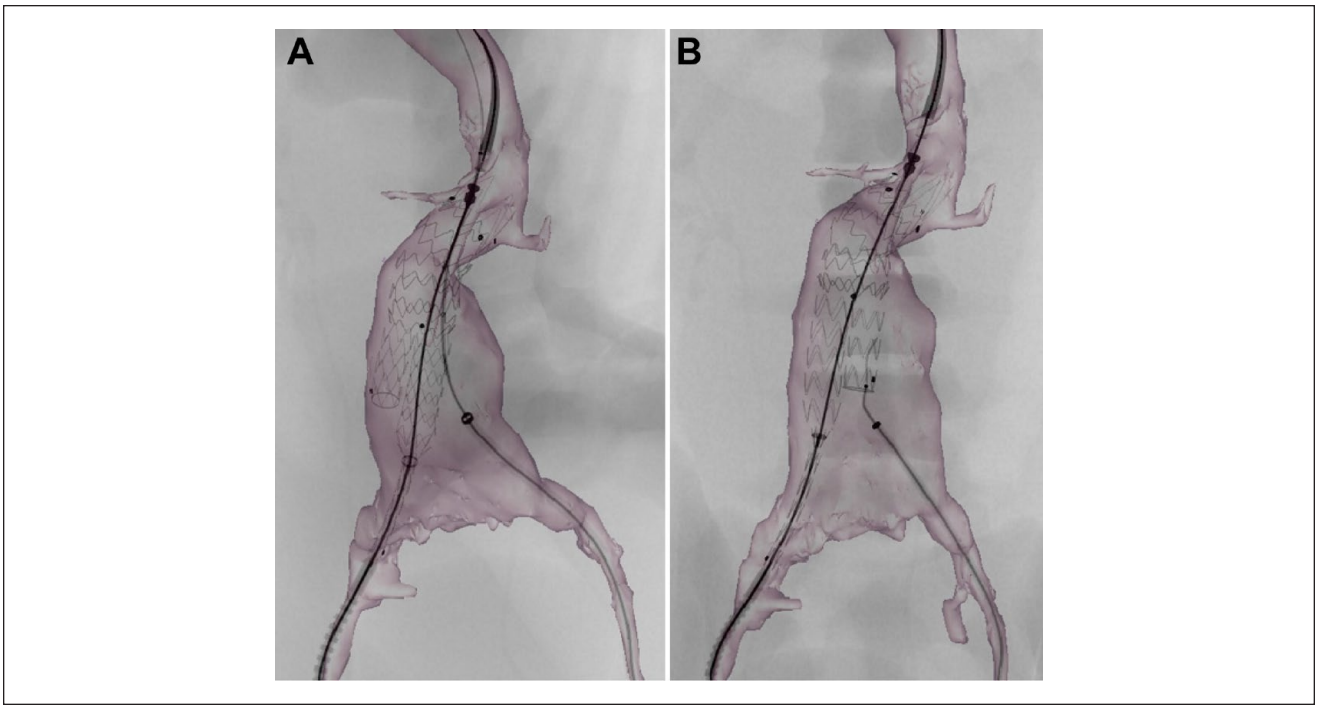

Figure 1. Preoperative rehearsal on the Procedure Rehearsal Studio software: stent-graft deployment in the (A) ballerina configuration and in the (B) standard fashion.

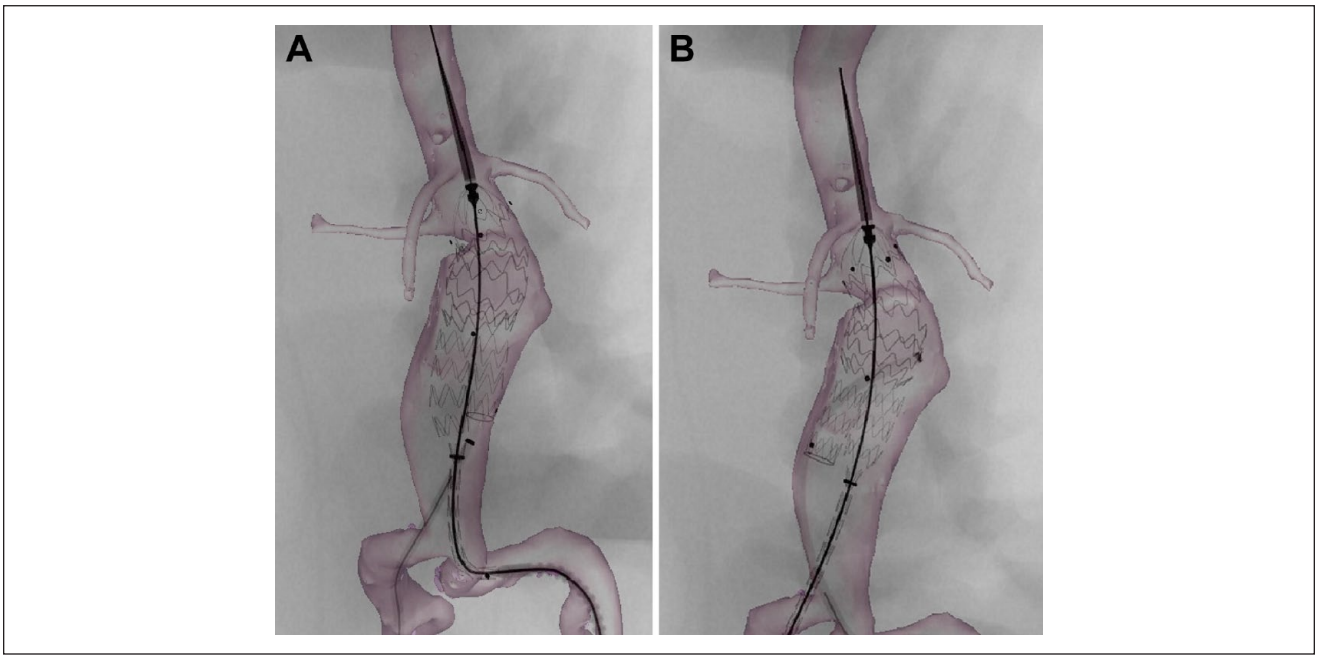

Figure 2. Preoperative rehearsal on the Procedure Rehearsal Studio software: stent-graft deployment in ballerina configuration introduced from (A) the left access and from (B) the right access.

zones) that could create technical problems, potentially restricting EVAR applicability.

This study examined the hypothesis that performance of PsR before eEVAR may be a valuable means of informing the decision between EVAR over open repair. In various domains of surgery, PsR allows a patient-tailored approach, enabling the surgeon and his/her team to perform and practice "real" cases on a virtual model of the actual patient prior to surgery.

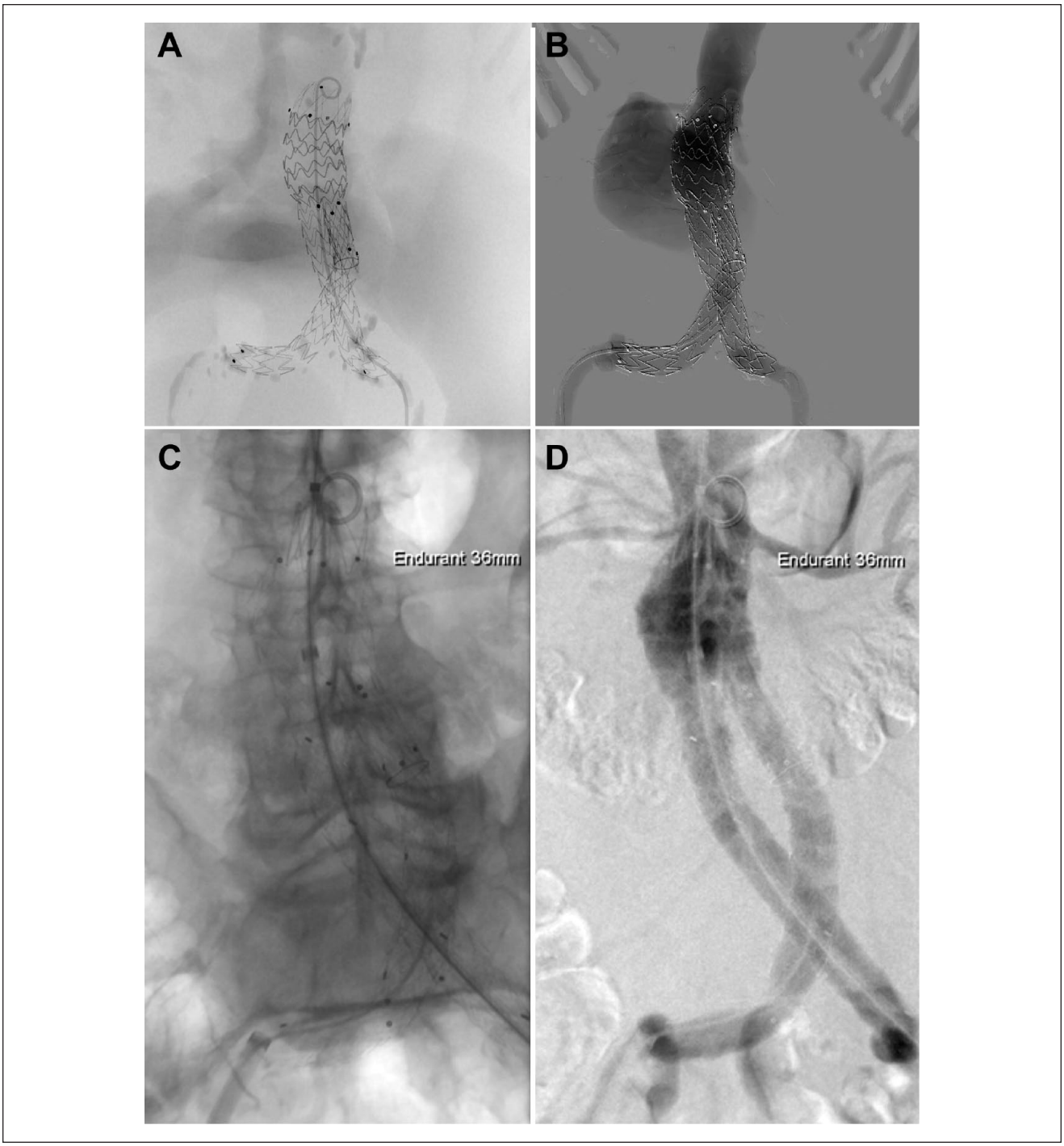

Figure 3. Final (A) radiography and (B) angiography at the preoperative rehearsal in the Procedure Rehearsal Studio software, showing type Ia endoleak. Final (C) radiography and (C) angiography at the end of the actual endovascular procedure, showing no endoleak.

The use of PsR has shown benefits in terms of team training, with great face validity, preoperative planning, and time effectiveness.[13] A recent randomized controlled trial concluded that PsR before elective EVAR can reduce perioperative errors and the number of angiograms required to deploy the stent-graft, thereby reducing delays in AAA cases and improving patient safety and procedural efficiency.[14] Moreover, PsR helps in planning angulations to achieve the best projection for visualization and land accurately vis-à-vis the renal arteries.[15–17] Precise proximal landing is essential in rAAA since such patients often have large aneurysms and challenging infrarenal necks.

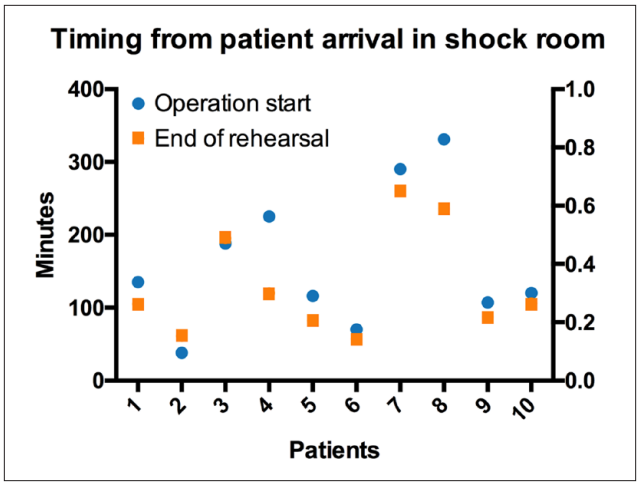

Figure 4. Time interval from patient arrival in the shock room to rehearsal completion and start of the actual endovascular procedure.

In our experience PsR with the PRS software proved to be a valuable and helpful tool to assess EVAR feasibility and to choose appropriate devices, the most appropriate access site for aortic main body introduction, and optimal projections for renal and hypogastric artery visualization. In terms of preoperative planning, statistically significant changes were not observed, but this is not necessary to justify the usefulness of PsR; rather it is of utmost importance to confirm the initial plan and strategy. The ability to simulate the contralateral gate tilting allowed advance planning before the actual procedure for the best combination of main body access and orientation. Nevertheless, preoperative PsR requires logistics, time investment, and dedicated skills. Moreover, 3D model reconstruction from CTA on patients with rAAAs and hemodynamic instability can be problematic due to insufficient contrast enhancement filling the aorta and visceral branches. CTA slice thickness, contrast quality, and presence of artifacts can negatively influence the time required for 3D reconstruction.

Attention must be paid also to real-life off-the-shelf availability of stent-graft devices, quite different from the virtual reality of PsR, where such limitations do not exist. In our experience stock availability of stent-graft components has a major influence on stent-graft selection, wherein mostly shorter main body stent-grafts are chosen, requiring the use of longer or more limb components.

Our results indicate that the aim of the study to assess feasibility of PsR in the emergency setting of rAAAs was clearly fulfilled. Modern operating theatres already allow image fusion of angiography and 3D CTA reconstruction.[18] The integration of simulation software to provide fast track segmentation-simulation and in situ data transfer represents a further step to increase the feasibility and success of eEVAR. Moving forward, close collaboration with simulation companies and engineers will go a long way toward improving hardware and software components and to implementing system buildup.

Conclusion

PsR in rAAA is feasible, with no time delay in eEVAR procedures when PsR is performed in parallel to a standard approach. PsR optimized endograft device deployment accuracy and orientation. The use of PsR before eEVAR could potentially decrease technical errors during procedure planning, optimize operative strategy, and reduce the number of stent-graft components and thus treatment costs.

Authors' Note

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Declaration of Conflicting Interests

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